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Fenpropathrin Summary Document
Registration Review: Initial Docket
June 2010

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Case # 7601

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Date

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This Preliminary Work Plan and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

1. *EFED Registration Review Problem Formulation for Fenpropathrin*. USEPA, June 16, 2010.
2. *Fenpropathrin. Human Health Assessment Scoping Document in Support of Registration Review*. USEPA, April 27, 2010.
3. *Fenpropathrin- ADDENDUM to D371484 Human Health Assessment Scoping Document in Support of Registration Review*. USEPA, June 10, 2010.
4. *PRD Appendix A: Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning – Fenpropathrin (127901)*. USEPA, June 2, 2009.
5. *Screening Level Estimates of Agricultural Uses of Fenpropathrin (127901).* USEPA, August 7, 2009.
6. *Fenpropathrin Review of Human Incidents*. USEPA, February 25, 2010.

All supporting documents for the registration review of Fenpropathrin are located in docket EPA-HQ-OPP-2010-0422 at www.regulations.gov.

I. PRELIMINARY WORK PLAN – Fenpropathrin

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/ .

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of fenpropathrin.

Fenpropathrin is a type II pyrethroid insecticide and acaracide registered for use on ornamentals and agricultural crops, which include apples, cantaloupes, grapefruit, grapes, oranges, pears, peppers, strawberries and tomatoes. Since fenpropathrin was first registered in 1989, it was not subject to a Reregistration Eligibility Decision (RED). In 1997, EPA assessed tolerances of fenpropathrin consistent with FQPA (62 *Fed. Reg.* 63,029, November 26, 1997).

Below is a summary of the issues relevant to the registration review of fenpropathrin and the data the Agency anticipates needing.

Anticipated Risk Assessment and Data Needs

The Agency anticipates conducting a comprehensive ecological risk assessment, including an endangered species risk assessment, for all uses of fenpropathrin. The Agency also anticipates conducting an occupational human exposure risk assessment. Further human health risk assessments may be needed if the Agency determines that there is residential bystander exposure or revises fenpropathrin's endpoints of toxicological concern.

Ecological Risk

- The most recent ecological risk assessment was completed in 2008 to support the new uses of fenpropathrin on bushberries, caneberries, olives, currants, peas, fruiting vegetables, stone fruits, tree nuts, pistachios, certain tropical fruits and barley.

- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether fenopropathrin's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

- The Agency anticipates needing the following data in order to conduct a complete ecological risk assessment, including an endangered species assessment for fenpropathrin:

    - GDLN 835.1230 or 825.1240 – Leaching and adsorption/desorption
    - GDLN 835.2240 – Photodegradation in Water
    - GDLN 835.4100 – Aerobic Soil Metabolism
    - GDLN 835.4200 – Anaerobic Soil Metabolism
    - GDLN 835.4300 – Aerobic Aquatic Metabolism
    - GDLN 835.4400 – Anaerobic Aquatic Metabolism
    - GDLN 835.6100 (footnote 7) – Environmental Chemistry Methods – soil
    - GDLN 835.6200 (footnote 7) – Environmental Chemistry Methods – water and sediment
    - GDLN 850.1010 Aquatic Invertebrate Acute Toxicity (*Hyalella azteca)*
    - GDLN 850.1400 – Fish Early-Life Stage (estuarine/marine)
    - GDLN 850.2100 –Avian Oral Toxicity (passerine species)
    - GDLN 850.4100 – Seedling Emergence (Tier II)[1]
    - GDLN 850.4150 – Vegetative Vigor (Tier II)[1]
    - GDLN 850.4400 – Aquatic Vascular Plant Growth (*Lemna spp.)* (Tier II)[1]
    - GDLN 850.5400 – Algal Toxicity Test (Tier II)[1]
    - Non-GDLN – Whole Sediment: Chronic Invertebrates (freshwater and estuarine/marine) (*Hyalella azteca*, *Chironomus dilutus*, and *Leptocheirus plumulosus)*

[1] Registrants may opt to conduct a Tier I study. However, any adverse effects (even if <25%) identified will necessitate a Tier II study. A Tier II study will enable the Agency to conduct an endangered species assessment for non-target plants.

- For a more detailed discussion of the anticipated ecological risk assessment and data needs, please refer to the *EFED Registration Review Problem Formulation for Fenpropathrin*, dated June 16, 2010. This document is located in the docket.

Human Health Risk

- The most recent comprehensive human health risk assessment for fenpropathrin was completed in 2008 to support the new uses of fenpropathrin on bushberries, caneberries, olives, currant, peas, fruiting vegetables, stone fruits, tree nuts, pistachios, certain tropical fruits and barley. In 2009, an abbreviated assessment was completed to evaluate a proposed low-volume use on citrus as a special local need in Florida.

- The Agency is investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms. A meeting of the FIFRA Scientific Advisory Panel (SAP) is planned for July 2010. For more information on the pyrethroid developmental neurotoxicity (DNT) requirement, see http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

- The toxicology database is incomplete with a data gap for immunotoxic effects (a new requirement for Part 158) and an outstanding 90-day inhalation study. The FQPA safety factor, which is based on the rat reproduction and developmental neurotoxicity (DNT) data for fenpropathrin, is currently 1X. However, based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. Therefore, the Agency is investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms. The FQPA safety factor will be re-evaluated for fenpropathrin following a final determination of the potential for increased susceptibility of infants and children to pyrethroid pesticides based on the results of all available data, including those human health data identified within this Preliminary Work Plan as anticipated as being needed.

- The existing residue chemistry database for fenpropathrin is adequate for risk assessment purposes.

- The tolerance expression in 40 CFR 180.466 will be reviewed during registration review to ensure that it appropriately covers the metabolites and degradates of fenpropathrin and that it specifies the residues to be measured for each commodity.

- In the 2008 risk assessment, dietary risk estimates (food and water) were below the Agency's level of concern. Therefore, the Agency does not anticipate conducting a new dietary risk assessment unless endpoints and safety factors for fenpropathrin are revised.

- Fenpropathrin has no residential uses. However, residential exposure could potentially result from the volatilization and transport of fenpropathrin from treated areas. The Agency will evaluate the need for a residential bystander inhalation risk assessment during registration review. The Agency is in the process of evaluating whether new policies or procedures are necessary to identify when and how to incorporate residential inhalation exposure in the Agency's risk assessments. If new policies or procedures are developed, the Agency may decide to conduct a bystander inhalation risk assessment.

- The Agency does not anticipate conducting an aggregate assessment for fenpropathrin in registration review unless dietary endpoints and safety factors are revised and/or new inhalation risks to residential bystanders need to be assessed.

- All occupational exposure scenarios have been assessed for fenpropathrin. However, the Agency anticipates reassessing occupational handler and post-application exposures for the use of fenpropathrin on ornamental plants in commercial nurseries and greenhouses. The ornamental plant uses were last assessed in 1993 and it is anticipated that these uses will need to be reassessed using currently available Pesticide Handler's Exposure Data (PHED) and/or Outdoor Residential Exposure Task Force (ORETF) data. In addition, the Agency is in the process of evaluating whether new policies or procedures are necessary to identify when and how to incorporate post-application inhalation exposure in the Agency's occupational risk assessments. If new policies or procedures are developed, the Agency may decide to conduct an occupational post-application risk assessment for all relevant scenarios.

- Fenpropathrin belongs to the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, deltamethrin, tau-fluvalinate, and lambda-cyhalothrin, among others. EPA developed a draft science policy document on the proposed common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009 http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a62df). This document was supported by the FIFRA SAP and is available in the docket. *See* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a1f8d7. EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the Stochastic Human Exposure and Dose Simulation (SHEDS) probabilistic exposure model, which are important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts will be reviewed by the FIFRA SAP in July, 2010. For information regarding EPA's efforts to evaluate the risk to pyrethroids. *See* http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

- The Agency anticipates requiring the following data in order to conduct a complete human health risk assessment for fenpropathrin:

    - GDLN 870.7800 – Immunotoxicity Study
    - GDLN 870.3465 – 90-Day Inhalation Study

- For a detailed discussion of the anticipated human health risk assessment and data needs for fenpropathrin refer to the *Fenpropathrin. Human Health Assessment Scoping Document in Support of Registration Review*, dated April 27, 2010 and the *Fenpropathrin- ADDENDUM to D371484 Human Health Assessment Scoping Document in Support of Registration Review*, dated June 10, 2010. These documents are located in the docket.

Other Anticipated Data Needs:

- GLDN 830.7050 UV/Visible Light Absorption – this study is a new data requirement under 40 CFR part 158 (Product Chemistry Data Requirements) for registration of a pesticide (food and non-food uses). The Agency anticipates requiring this study to obtain basic information about the compound's identity/composition and the wavelengths at which the compound may be susceptible to photochemical degradation.

Endocrine Disruptor Screening Program

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Fenpropathrin is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide

chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/ .

Timeline

The Agency has created the following estimated timeline for the completion of the fenpropathrin registration review.

Registration Review for Fenpropathrin Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the docket	
Open Docket and Public Comment Period	2010 – June
Close Public Comment	2010 – August
Case Development	
Final Work Plan	2010 – November
Issue DCI	2011 – July – Sept.
Data Submission	2013 – July – Sept.
Open Public Comment Period for Preliminary Risk Assessments	2015 – Jan. – March
Close Public Comment Period	2015 – April - June
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	2015 – July - Sept.
Close Public Comment Period	2015 – Oct. – Dec.
Final Registration Review Decision and Begin Post-Decision Follow-up	2016
Total (years)[1]	6

1 An assessment of the potential cumulative risk from the pyrethroid class of insecticides may impact this time estimate.

Guidance for Commenters

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments, as well as any additional information or data provided in a timely manner, prior to issuing a final work plan for the fenpropathrin case.

Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum

Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to fenpropathrin compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure, compared to the general population.

Water Quality

Fenpropathrin is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. However, the pyrethroids as a group have been identified as a cause for impairment for three water bodies in Central Valley, CA: Del Puerto Creek, Ingram Creek Site (confluence with Hospital Creek to Hwy 33 crossing) and second Ingram Creek Site (confluence with San Joaquin River to confluence with Hospital Creek). Nonetheless, no Total Maximum Daily Loads (TMDL) have been developed for fenpropathrin, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm) in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Additional Information

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining risk assessments, including any species-specific ecological effects determinations. The Agency is interested in receiving the following information:

1. Confirmation on the following label information.
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates
    e. frequency of application, application intervals, and maximum number of applications per season and per year
    f. geographic limitations on use
2. Use or potential use distribution (e.g., geographical distribution of relevant uses).
3. Use history.
4. Median and 90th percentile reported use rates (lb/A, lb 1K sq.ft) from usage data – national, state and county.
5. Application timing (date of first application and application intervals) by use – national, state, and county.
6. Usage/use information for non-agricultural uses.
7. Directly acquired county-level usage data (not derived from state level data).
    a. maximum reported use rate (lb/A) from usage data – county
    b. median and 90th percentile number of applications – county
    c. total pounds per year – county
    d. the year the pesticide was last used in the county/sub-county area
    e. the years in which the pesticide was applied in the county/sub-county area
8. Typical application interval (days).
9. State or local use restrictions.
10. Ecological incidents specific to fenpropathrin (non-target plant damage and avian, fish, reptilian, amphibian, mammalian mortalities, and bee or beneficial insect mortalities) not already reported to the Agency.
11. Monitoring data.
12. Any adverse effects in honey bees or other beneficial insects associated with the use of fenpropathrin products.

Next Steps

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner and then expects to issue a Final Work Plan in November of 2010 for fenpropathrin.

II. FACT SHEET

Background Information

- Fenpropathrin registration review case number: 7601
- Fenpropathrin PC Code: 127901; CAS # 39515-41-8
- Fenpropathrin was first registered in the United States in 1989.
- Technical registrant: Valent U.S.A. Corporation
- There are 8 FIFRA Section 3 active product registrations, which includes one technical use registration.
- Pesticide Re-evaluation Division Contact: Avivah Jakob (Jakob.kathryn@epa.gov)
- Registration Division Contact: Olga Odiott (Odiott.olga@epa.gov).

Use and Usage Information

For additional usage information and use details refer to *Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning – Fenpropathrin (127901)*, dated June 2, 2009, which can be located in the fenpropathrin docket.

- Fenpropathrin is a pyrethroid insecticide registered for use on ornamentals and on a variety of agricultural uses including apples, cantaloupes, grapefruit, grapes, oranges, pears, peppers, strawberries and tomatoes.
- The largest agricultural uses of fenpropathrin are strawberries, oranges, pears and grapefruit. The Agency estimates that the maximum percent crop treated of these commodities are respectively 50%, 30%, 20% and 20%.
- Fenpropathrin is registered for use to control a variety of arthropods including aphids, worms, moths, beetles, mites, spiders, thrips, flies, fleas and other pests in agricultural and ornamental plant situations.
- Fenpropathrin is formulated as an emulsifiable concentrate and a pressurized liquid.
- Fenpropathrin can be applied by aircraft, airblast ground sprayer, broadcast ground sprayer and aerosol can.

Pending and Recent Actions

- The Agency is currently reviewing the proposed new use of fenpropathrin on tropical fruits. The Agency anticipates making its registration decision in November 2010.

- In March 2009, the Agency established tolerances for residues of fenpropathrin in or on almond hulls, sweet cherry, tart cherry, stone fruits (crop group 12 – except cherries), tree nuts (crop group 14), pistachio, avocado, black sapote, canistel, mamey, sapote, mango, papaya, sapodilla, star apple, caneberry and olive.

Ecological Risk Assessment Status

The primary environmental concerns identified in previous risk assessments were chronic risk to birds and mammals, and acute and chronic risk to fish, aquatic invertebrates including benthic organisms, reptiles, and terrestrial and aquatic phase amphibians. Fenpropathrin is also toxic to honeybees; therefore, risk to beneficial insects was assumed.

For a detailed discussion of previous ecological risk assessments, please refer to the *EFED Registration Review Problem Formulation for Fenpropathrin*, dated June 16, 2010. This document is located in the docket.

Human Health Risk Assessment Status

The following are key findings of the human health risk assessments conducted to support fenpropathrin registered uses. For a detailed discussion of the human health risk assessment status, please refer to the *Fenpropathrin. Human Health Assessment Scoping Document in Support of Registration Review*, dated April 27, 2010 and the *Fenpropathrin- ADDENDUM to D371484 Human Health Assessment Scoping Document in Support of Registration Review*, dated June 10, 2010. These documents are located in the docket.

Hazard Characterization

- Fenpropathrin exhibits high acute toxicity through the oral and dermal routes of exposure. Fenpropathrin is a mild eye irritant, non-irritating to the skin and is not a skin sensitizer. Because of fenpropathrin's low-vapor pressure, the methods used in previous inhalation studies did not generate inhalation exposures high enough to elicit a toxic response. Therefore, acute inhalation toxicity has not been determined for fenpropathrin.

- Fenpropathrin is classified as "not likely to be carcinogenic to humans" based on carcinogenicity studies in rats and mice.

- In the prenatal developmental studies in rats and rabbits, the reproduction study in the rat and the developmental neurotoxicity (DNT) study, fenpropathrin had no adverse effects on offspring in the absence of maternal effects. Because there was no evidence of increased susceptibility in fetuses following *in utero* exposure as compared to maternal animals and no concerns regarding exposure estimates underestimating actual exposures, in the 2008 assessment the Agency reduced the FQPA Safety Factor to 1X. However, based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. The Agency is investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms.

Dietary Risk

- In EPA's 2008 risk assessment, dietary risk (food and water) estimates from all registered fenpropathrin uses were below the Agency's level of concern.

Residential and Recreational Risk

- There are no registered residential uses of fenpropathrin; therefore, residential exposure has not been previously assessed.

Aggregate Risk

- A residential exposure assessment has not been previously conducted because it is believed that fenpropathrin use does not result in residential exposure. Therefore, aggregate risk estimates are equivalent to the dietary risk estimates described above.

Occupational Risk

- Past fenpropathrin risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED) and the Agricultural Reentry Task Force (ARTF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied and there is no regulatory barrier for continued reliance on these studies.

- All occupational exposures resulting from fenpropathrin use have been previously evaluated. The results of previous occupational handler exposure assessments showed no risk estimates of concern.

Cumulative Assessment

- Fenpropathrin is a member of the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, tau-fluvalinate, bifenthrin, and lambda-cyhalothrin, among others. EPA developed a draft science policy document on the proposed common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009;http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a

62df). This document was supported by the FIFRA Scientific Advisory Panel (SAP) and EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the Stochastic Human Exposure and Dose Simulation (SHEDS) probabilistic exposure model which is important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts will be reviewed by the FIFRA SAP in July, 2010. For information regarding EPA's efforts to evaluate the risk to pyrethroids, http://www.epa.gov/pesticides/cumulative/ .

Incidents

- A preliminary review of the Ecological Incident Information System (EIIS) and the Avian Incident Monitoring System (AIMS) Database identified one incident for fenpropathrin. Fenpropathrin was classified as a "highly probable" cause for an incident in 1996 involving hundreds of fish mortalities (shad, catfish and carp) after fenpropathrin application to cotton.

- An updated review of fenpropathrin human incident reports was prepared by consulting the OPP Incident Data System (IDS) and the Centers for Disease Control and Prevention/ National Institute for Occupational Safety and Health Sentinel Event Notification System for Occupational Risk-Pesticides. In the United States, from 2002 to the present, 12 incidents were reported for fenpropathrin. Of those 12 reported incidents, only six incidents were identified as definitely, probably or possibly caused by fenpropathrin exposure. Three of the six incidents were related to occupational pesticide application while the other three did not involve pesticide application (further details are unknown). The health effects identified include dermal, neurological and ocular. Based on the low severity and low number of incident cases, there does not appear to be a concern at this time that would warrant further investigation.

Tolerances and International Harmonization

- Tolerances are established under 40 CFR 180.466 for residues of fenpropathrin that result from agricultural uses. Tolerances are established in terms of fenpropathrin. There are no Canada maximum residue limits (MRL) for fenpropathrin. Codex MRLs are not harmonized with U.S. tolerances for cattle (meat and meat byproducts), eggs, milk, poultry (meat and meat byproducts), eggplants, dry chili peppers, gherkin, and tea (green and black). Some of the U.S. tolerances that are not harmonized with Codex MRLs may also not be harmonized with Mexico MRLs because Mexico either adopts US tolerances or Codex MRLs for import purposes.

Data Call-In Status

- No data call-ins (DCIs) have been issued for fenpropathrin.

Labels

- Active Section 3 labels for fenpropathrin can be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home .